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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/530,146	03/31/2005	Martin A Smith	58142(45858)	2874
21874 7590 12/17/2007 EDWARDS ANGELL PALMER & DODGE LLP P.O. BOX 55874 BOSTON, MA 02205			EXAMINER TUNG, JOYCE	
			ART UNIT 1637	PAPER NUMBER
			MAIL DATE 12/17/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/530,146	Applicant(s) SMITH ET AL.	
	Examiner Joyce Tung	Art Unit 1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 October 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-35 and 66 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-35 and 66 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The applicant's response filed 10/12/07 to the Office action mailed 5/16/07 has been entered. Claims 1-35 and 66 are pending.

1. The rejection of claims 3, 11, 21, and 23-24 under 35 U.S.C. 112, second paragraph is withdrawn because of the applicant's amendment.
2. The rejection of claim 13 under 35 U.S.C. 103(a) as being unpatentable over Mitchell et al. (WO 00/21973, issued April 20, 2000) in view of Burgoyne (5,496,562, issued March 5, 1996) is withdrawn because of the applicant's amendment.
3. Regarding the Notice of References Cited (PTO-892) as mentioned in the response filed 10/12/07, the PTO-892 was not attached, but it is checked in PTO-326 which was an error.
4. Claims 1-12, 14-35 and 66 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Mitchell et al. (WO 00/21973, issued April 20, 2000) in view of Burgoyne (5,496,562, issued March 5, 1996).

Mitchell et al. disclose the method steps (a)-(e) as recited in instant claim 1 (See pg. 2, third paragraph) and the method steps as recited in claim 4 (See pg. 2, third paragraph). The nucleic acid is retained by the filter substantially in the absence of ionic interaction (See column 2, last paragraph), and by physically retarding the movement of the nucleic acid down the filter (See pg. 3, first paragraph). The nucleic acid is heated to an elevated temperature, whilst retained by the filter prior to elution and the temperature is about 90⁰C, (See pg. 3, second paragraph, pg. 6, first paragraph, pg. 12, first paragraph and pg. 25, experiment 6). There is a solution for rupturing intact whole cells to leave condensed nuclear material and a lysis solution for lysing nuclear material (See pg. 3, third paragraph). The sample comprises whole blood,

which has been treated with a red blood cell lysis solution, whilst the white cells containing the nucleic acid are retained by the filter as a retentate (See pg. 6, third paragraph). A filter material is selected which provides no barrier to cells, but enables the cells to be retained by the filter as a retentate (See pg. 6, second paragraph). The pore size of the filter is 4.5um (See pg. 11, table1). The filter used in the method comprises a plurality of fibers and has a substantially disordered structure, the fiber diameters are selected from the range of 1um to 10 um (See pg. 9, fourth paragraph). The fiber is glass fiber, silica based or plastic based fiber (See pg. 10, first paragraph). It is possible to isolate nucleic acid in the absence of a chaotrope (See pg. 10, second paragraph). Genomic DNA is a desired target or nucleic acid is RNA (See pg. 15, fourth paragraph).

Mitchell et al. do not disclose the method steps (f)-(g) as recited in instant claim 1.

Burgoyne discloses that the blood-stained paper was dried, and sent through the ordinary mail so that it spent at least three days in the mail, and had the DNA extracted from it (See column 4, lines 41-45). A card loaded with a DNA sample is air dried at room temperature (See column 5, lines 43-44).

One of ordinary skill in the art would have been motivated to apply the method steps of drying the solid phase medium with the cell lysate comprising nucleic acid and storing the dried solid phase medium with the nucleic acid because it would have been useful for long time storage, such as 36 months (See column 4, lines 21-25) or four years (See column 5, lines 1-4). It would have been prima facie obvious to apply the method steps (f)-(g) as recited in instant claim 1.

The response argues that Mitchell et al. disclose that the SDS and TE are added separately and filtered to waste, e.g. in Mitchell, the lysis solutions are added sequentially in order to function. However, the limitation as recited in the instant claim is “contacting the cellular retentate with a solution comprising a surfactant or detergent”. The limitation does not exclude that there is only one solution containing all the surfactants or detergents. Thus one of ordinary skill in art would have more than one chance to add more than one different solution to optimize a condition for isolating and storing nucleic acid.

The response also argues Burgoyne uses a chemical composition of the base, chelator, detergent and uric/urate salt that is already deposited on the solid matrix. The limitation as recited in the instant claim is “drying the solid phase medium with the cell lysate comprising the nucleic acid”. The limitation does not exclude that the solid phase does not have the chemical composition.

The response argues that in Mitchell the DNA dried may be sheared... drying of the filter may be avoided. However, because Mitchell does not disclose the method steps (f)-(g) as recited in instant claim 1, and there is no limitation recited in the claims that an isolated DNA is sheared, the reference of Burgoyne is applied in that Burgoyne discloses that the blood-stained paper was dried, (See column 4, lines 41-45) and a card loaded with a DNA sample is air dried at room temperature (See column 5, lines 43-44).

The response argues that Burgoyne discloses drying the matrix, it fails to mention adding a solution to the already applied sample and instead, the solution of Burgoyne is added to the

matrix and dried prior to application of the sample. The argument stated herein does not correspond to any limitations recited in the claims.

Based upon the discussion above, the reference of Mitchell in view of Burgoyne is properly applied. Thus, the rejection is maintained.

NEW GROUND REJECTION NECESSITATED BY THE AMENDMENT

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mitchell et al. (WO 00/21973, issued April 20, 2000) in view of Burgoyne (5,496,562, issued March 5,

1996) as applied to claims 1-12, 14-35 and 66 above, and further in view of Mullis (5,187,083, issued Feb, 16, 1993).

The teachings of Mitchell et al. and Burgoyne et al. are set forth in section 4 above. Mitchell et al. and Burgoyne do not disclose the size of the filter pore as recited in claim 13.

Mullis discloses a method for obtaining substantially purified DNA from a biological sample (See column 3, lines 21-22). The filter includes a surface that reversibly and specifically retains DNA. The pore size is from about 0.2 microns to about 0.8 microns. A preferred filter comprises a membrane filter comprised of cellulose acetate and nitrocellulose having a pore size of 0.45 microns (See column 3, lines 44-54, column 7, line 44-45, column 10, lines 16-29, column 15, lines 25).

One of ordinary skill in the art would have been motivated to apply the filter of Mullis with the pore size which is from about 0.2 microns to about 0.8 microns because the filter of Mullis is used in obtaining substantially purified DNA from a biological sample (See column 3, lines 21-22). It would have been prima facie obvious to apply the filter of Mullis with the pore size which is from about 0.2 microns to about 0.8 microns for isolating nucleic acid as claimed.

Summary

7. No claims are allowed.
8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

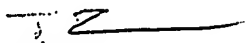
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joyce Tung whose telephone number is (571) 272-0790. The examiner can normally be reached on Monday - Friday, 8:30-5:00.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Joyce Tung 
December 10, 2007


KENNETH R. HORLICK, PH.D
PRIMARY EXAMINER

12/13/07